

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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:
FEDERAL TRADE COMMISSION, STATE OF NEW :
YORK, STATE OF CALIFORNIA, STATE OF :
OHIO, COMMONWEALTH OF PENNSYLVANIA, : 20cv706 (DLC)
STATE OF ILLINOIS, STATE OF NORTH :
CAROLINA, and COMMONWEALTH OF : OPINION AND ORDER
VIRGINIA, :
:
Plaintiffs, :
:
-v- :
:
VYERA PHARMACEUTICALS, LLC, AND :
PHOENIXUS AG, MARTIN SHKRELI, :
individually, as an owner and former :
director of Phoenixus AG and a former :
executive of Vyera Pharmaceuticals, :
LLC, and KEVIN MULLEADY, individually, :
as an owner and former director of :
Phoenixus AG and a former executive of :
Vyera Pharmaceuticals, LLC, :
:
Defendants. :
:
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DENISE COTE, District Judge:

The Federal Trade Commission ("FTC") and seven states bring claims for violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; § 5(a) of the FTC Act, 15 U.S.C. § 45(a); and various state statutes. They allege that Vyera Pharmaceuticals, LLC ("Vyera"), together with its parent company, Phoenixus, AG ("Phoenixus"), and two of the companies' owners and executives, Martin Shkreli and Kevin Mulleady (together, the "Individual Defendants") designed and implemented a comprehensive scheme to block lower-cost generic drug competition to Daraprim, a branded drug used to treat the potentially fatal infection toxoplasmosis. As alleged, this unlawful scheme enabled the defendants to raise the price of Daraprim from \$17.50 per tablet to \$750 per tablet overnight, even though Daraprim had long ago lost its patent protection.

On May 22, 2020, the defendants moved to dismiss all of the claims against them pursuant to Rule 12(b) (6), Fed. R. Civ. P. For the reasons stated below, the motions to dismiss are denied as to all claims except the claim brought under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

Background

The following facts are taken from the Amended Complaint. They are assumed to be true for the purpose of deciding these motions.

I. Generic Pharmaceutical Drugs

Generic drugs are chemically identical versions of branded drugs. After the patent on a branded drug has expired, a generic drug may compete with its branded counterpart. Generic versions of branded drugs are usually sold at lower prices and that price competition is critical to lowering the price of prescription drugs in the United States.

To promote competition, governments have enacted drug substitution laws that encourage and facilitate the substitution of generic drugs for their branded equivalents.¹ While a company

¹ The regulatory scheme employed by the FDA is governed by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b) (2) and 355(j) and 35 U.S.C. § 271(e).

seeking to market a branded drug must first file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the pharmaceutical product, a company seeking to market a generic version of the branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA that affords an expedited process for gaining FDA approval. 21 U.S.C. § 355(j).

An ANDA applicant must demonstrate bioequivalence between the generic drug and its branded counterpart, i.e. that there is no significant difference in the rate and extent to which the drug's active ingredient becomes available to the body. Id. §§ 355(j) (2) (A) (iv), 355(j) (8) (B) (i). To conduct bioequivalence testing, an ANDA applicant must acquire substantial quantities of the branded drug to which it compares its generic product. An ANDA applicant normally can obtain sufficient samples of the branded drug to conduct bioequivalence testing by purchasing samples through established distribution channels such as drug wholesalers.

An ANDA applicant also must secure a supply of the branded drug's active pharmaceutical ingredient ("API"), which is the ingredient that provides the drug's pharmacological activity. The applicant must identify its API supplier to the FDA. The API supplier's product, manufacturing process, facility, and quality controls must receive FDA approval for an ANDA

application to move forward. If an ANDA applicant purchases API from a supplier whose manufacturing of that API has already been approved by the FDA, the FDA's approval process of the ANDA application may be expedited by a period of months or years.

II. Vyera

A. The Founding of Vyera and Acquisition of Daraprim Rights

Martin Shkreli made his debut in the pharmaceutical industry in 2011 when he founded Retrophin, Inc. Retrophin acquired a drug named Thiola, raised its price by 2,000%, and restricted its distribution to prevent competition from generic drugs. In 2014, Shkreli was removed from Retrophin by the company's board of directors for misconduct.

In 2014, Shkreli launched Vyera with the help of Kevin Mulleady. Vyera is a wholly-owned subsidiary of Phoenixus. This Opinion refers to Vyera and Phoenixus collectively as "Vyera," unless otherwise specified.

In April 2015, Vyera made an unsolicited bid to Impax Laboratories, Inc. ("Impax") for the U.S. rights to the branded drug Daraprim. Daraprim is used to treat toxoplasmosis, an infection that can be fatal for immunocompromised individuals, particularly those with cancer or HIV/AIDS. Daraprim was approved by the FDA in 1953. In 2010, Daraprim was sold for \$1 per tablet. Between 2010 and 2015, its price increased to \$13.50 per tablet. Daraprim's API is pyrimethamine.

Impax had acquired the rights to Daraprim in March 2015, only one month before Impax received Vyera's bid. Impax assessed Daraprim, then priced at \$13.50 per tablet, as an asset with declining annual revenues of \$5 million or less. In June 2015, Impax developed a restricted distribution system for Daraprim and raised its price from \$13.50 to \$17.50.

On August 7, 2015, Vyera acquired the U.S. rights to Daraprim for \$55 million. This price was triple Impax's net-present-value assessment of Daraprim and more than 11 times Daraprim's annual net revenues.

The day after finalizing the deal, Vyera raised the price of Daraprim from \$17.50 to \$750 per tablet -- an increase of more than 4,000%. At the time of Vyera's acquisition of Daraprim, Mulleady informed Vyera's employees that it was Vyera's "#1 priority" to establish a restricted distribution system similar to that employed for Thiola at Retrophin.

Daraprim's price increase quickly gained public attention. In November 2015, the Senate Special Committee on Aging (the "Committee") launched a bipartisan investigation into dramatic price increases of several off-patent drugs, including Daraprim. The Committee heard testimony from Vyera executives confirming that Vyera built a restricted distribution system for Daraprim to block generic drug competitors from gaining access to Daraprim and conducting bioequivalence testing. The Committee

found that Vyera's restricted distribution of Daraprim was part of Vyera's plan to "defend its shocking price increase and subsequent increased revenue against potential competition."

B. Anti-Competitive Conduct

The Amended Complaint describes a sophisticated scheme to depress competition by generic drug manufacturers with the branded drug Daraprim. To effect this scheme, Vyera entered into three categories of contractual agreements: the restricted distribution agreements, exclusive supply contracts, and data-blocking agreements.

i. Restricted Distribution System

Through a restricted distribution system, the defendants sought to impede access to Daraprim and thereby prevent generic drug manufacturers from obtaining sufficient quantities of Daraprim to conduct bioequivalence testing. Vyera uses ICS, a third-party logistics provider, to receive Daraprim from Vyera's manufacturer and ship it to one of Vyera's four approved distributors, one of which is Optime Care Inc. ("Optime"). ICS is not permitted to sell Daraprim to any other purchaser without Vyera's approval.

In turn, Vyera's contracts with its four distributors permit them to sell Daraprim only to specific types of purchasers, namely specific hospitals, government purchasers, specialty pharmacies, and state AIDS Drug Assistance programs.

None of the contracts between Vyera and its distributors permit sales to generic pharmaceutical companies absent Vyera's approval.² Vyera compensates its distributors by paying them a percentage of Daraprim's wholesale acquisition cost (the "WAC")³ for each sale that it makes.

Vyera also imposes resale restrictions on the downstream purchasers to whom its distributors sell, i.e. hospitals and pharmacies. For instance, in May 2018, Vyera entered a contract with its distributor Optime that requires hospitals purchasing Daraprim to guarantee that Daraprim would not be resold "for any reason unless approved in writing by Vyera or its designee." Vyera also has direct agreements with hospitals and pharmacies that require them to use Daraprim only to treat hospital patients or patients with a prescription.

In addition to these resale restrictions, Vyera has limited the quantity of Daraprim that approved purchasers may acquire from distributors. A generic competitor needs between 5 to 10 bottles of Daraprim to conduct bioequivalence testing. Vyera limits distributors from selling more than 5 bottles of Daraprim

² The Amended Complaint does not specify precisely when the restrictive distribution contracts were executed or when they expire, but does allege they are still in effect.

³ The WAC is the publicly available list price for drugs published by the industry. Astrazeneca AB v. Apotex Corp., 985 F. Supp. 2d 452, 468 n.12 (S.D.N.Y. 2013)

to a single customer absent Vyera's approval. As recently as August 2019, Shkreli and Mulleady discussed further restricting the sales of Daraprim to one bottle at a time.

ii. Exclusive Supply Contracts

Vyera has entered into exclusive supply contracts with manufacturers of pyrimethamine to preclude others from obtaining access to an FDA-approved pyrimethamine manufacturer. After negotiations lasting over a year, in January 2017, Fukuzyu Pharmaceutical Co., Ltd. ("Fukuzyu") agreed to a contract -- still in force today -- that gives Vyera the exclusive U.S. rights to Fukuzyu's supply of pyrimethamine for human use. Vyera informed Fukuzyu that the exclusivity provision was intended to prevent generic pharmaceutical competitors from purchasing pyrimethamine.

After learning that another company, RL Fine Chem ("RL Fine"), was preparing to seek FDA approval for the manufacture of pyrimethamine, Vyera entered an exclusive supply agreement with RL Fine in November 2017. Pursuant to that agreement, Vyera was obligated to pay RL Fine a percentage of its Daraprim net revenues whether or not it received API from RL Fine and whether or not RL Fine ever received FDA approval for the production of the API. Over the course of just a few years, Vyera paid RL Fine millions of dollars but never received any pyrimethamine from it or sought approval by the FDA for use of

RL Fine-manufactured pyrimethamine in Daraprim. Invoking their contract, Vyera directed RL Fine to cease supplying pyrimethamine to two manufacturers of generic drugs.⁴

Vyera also contacted another company that has sought FDA approval for the manufacture of pyrimethamine, Ipcia Laboratories Ltd. ("Ipcia"). When Ipcia informed Vyera that the FDA had banned imports of Ipcia's pyrimethamine due to manufacturing deficiencies, Vyera informed investors that this ban would cause "significant disruption" and delay to generic competitors planning or hoping to use Ipcia as a pyrimethamine supplier.

iii. Data-Blocking Agreements

Vyera has entered into data-blocking agreements with two of its distributors. Pursuant to these agreements, Vyera pays these distributors a fee in exchange for their agreement not to sell their sales data to aggregators of market data. One distributor receives a fixed monthly fee, while the other receives a percentage of Daraprim's WAC per unit sold. The Amended Complaint alleges that these data-blocking agreements prevent competitors from assessing the market size and opportunity for competing with Vyera in its distribution of Daraprim.

⁴ Recently, on October 25, 2019, following receipt of several discovery requests from the FTC, Vyera paid RL Fine to terminate their agreement.

C. Generic Drug Competitors

The Amended Complaint alleges that the restrictive distribution system, together with the exclusive supply contracts and data-blocking agreements, have impeded the entry of generic drug competitors into the Daraprim market. Of four potential competitors, one has abandoned its efforts, two have been so delayed they are still awaiting approval, and one only recently succeeded in obtaining FDA approval.

The one company that has succeeded in bringing a generic product to market began developing its generic product in 2013, several years prior to Vyera's acquisition of Daraprim. It was therefore able to secure at least a limited supply of Daraprim. After Vyera acquired Daraprim, Vyera's restrictions on the resale of Daraprim and its control of RL Fine and Fukuzyu as suppliers of the API, however, substantially delayed and interfered with the company's application for FDA approval. It was not until February 28, 2020, which is after the filing of this action, that the FDA granted approval for the generic drug.

Two other companies have filed ANDA applications and are still awaiting approval. The Amended Complaint describes in detail how Vyera's web of contracts has delayed their applications and FDA approval. Since that web remains largely undisturbed, the Amended Complaint also explains the challenges that currently exist for any manufacturer of generic drugs that

needs to conduct bioequivalence testing or needs access to an approved supplier of Daraprim's API.

III. The Individual Defendants

The Amended Complaint alleges that Vyera's restricted distribution system, exclusive supply contracts, and data-blocking agreements were designed and implemented by the Individual Defendants Martin Shkreli and Kevin Mulleady. Both men continue to hold influence over Vyera.

A. Shkreli

Shkreli is the founder of Vyera and the founder, former chairman, and largest shareholder of Phoenixus, Vyera's parent company.⁵ Shkreli currently controls a substantial minority share position in Phoenixus. Shkreli was the CEO of Vyera until December 2015, when he was arrested for securities fraud. Shkreli has been incarcerated since September 2017 and is currently serving a seven-year sentence.

In addition to conceiving of the generic-blocking strategy, the Amended Complaint alleges that Shkreli has been and continues to be personally involved in Vyera's operations. For instance, in August 2017, just one month prior to his incarceration, Shkreli drafted written communications to RL Fine to request an exclusive supply contract for pyrimethamine.

⁵ The Phoenixus board of directors controls Vyera, which does not have a board of directors.

Since his incarceration, Shkreli has remained in regular contact with Mulleady and others at Vyera through telephone calls, emails, in-person prison visits, and WhatsApp messaging. From June to December 2019 alone, Shkreli exchanged many hundreds of emails with Mulleady and others at Vyera to discuss strategies for maintaining Vyera's restricted distribution system. Such communications include discussions with Mulleady in August 2019 about implementing a one bottle limit on the distribution of Daraprim at any one time.

B. Mulleady

Mulleady began working with Shkreli in 2011 at one of Shkreli's now defunct hedge funds. Mulleady assisted Shkreli in founding both Retrophin and Vyera. At Vyera, Mulleady initially was employed as managing director and chief of staff to Shkreli. Although Mulleady's employment at Vyera was terminated in 2016 shortly after Shkreli's arrest, Mulleady returned to Vyera in the summer of 2017 as Vyera's CEO and a Phoenixus board member.

As CEO of Vyera, a position Mulleady held until March 2019, Mulleady managed the network of agreements that allowed Vyera to block generic competition to Daraprim. In 2017, for example, Mulleady initiated an audit of all Daraprim purchasers. Upon learning that one first-time purchaser of Daraprim had acquired five bottles of the drug, which approached the amount of Daraprim necessary for bioequivalence testing, Mulleady

repurchased all five bottles at a price significantly above-market. In 2019, it was Mulleady who was responsible for negotiating Vyera's exclusivity contract with RL Fine. Mulleady remains the chairman of the Phoenixus board of directors and a Phoenixus shareholder.

IV. Procedural History

The FTC and New York state filed this action on January 27, 2020. On April 14, the Amended Complaint was filed, which added California, Illinois, North Carolina, Ohio, Pennsylvania and Virginia as plaintiffs. The Amended Complaint alleges violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; § 5(a) of the FTC Act, 15 U.S.C. § 45(a);⁶ the New York Donnelly Act, N.Y. Gen. Bus. Law § 340 et seq.; the New York Executive Law, N.Y. Exec. Law § 63(12); the California Cartwright Act, CA Bus. & Prof. Code § 16700 et seq.; the California Unfair Competition Act, CA Bus. & Prof. Code § 17200; the Illinois Antitrust Act, 740 ILCS 10/1 et seq.; the North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1, et seq.; the Ohio Valentine Act, Ohio Rev. Code Chpt. 1331; the Pennsylvania UTPCPL, 73 P.S. §§ 201-3, 201-2(4) (xxi) and 201-4; the Pennsylvania Common Law Doctrine against Restraints of Trade; and the Virginia Antitrust Act, Virginia Code § 59.1-9.1 et seq.

⁶ The FTC's antitrust claims are brought pursuant to the FTC Act. The states bring their federal claims under the Sherman Act.

The plaintiffs seek declaratory and injunctive relief, as well as equitable monetary relief.

On May 22, the defendants moved to dismiss the Amended Complaint in its entirety. The same day, the defendants filed a joint motion to stay discovery. The motion to stay discovery was denied on June 15. The defendants' motions to dismiss became fully submitted on July 27. The period for document discovery is scheduled to conclude on August 28, 2020. The remainder of the schedule for this litigation will be set at a September 11 conference.

Discussion

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Geffner v. Coca-Cola Co., 928 F.3d 198, 199 (2d Cir. 2019) (citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Charles v. Orange Cty., 925 F.3d 73, 81 (2d Cir. 2019) (citation omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Empire Merchs., LLC v. Reliable Churchill LLLP, 902 F.3d 132, 139 (2d Cir. 2018) (citation omitted). The plaintiff must plead enough facts to "nudge[] [its] claims across the line

from conceivable to plausible." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

When a party moves to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6), Fed. R. Civ. P., a court must "constru[e] the complaint liberally, accept[] all factual allegations as true, and draw[] all reasonable inferences in the plaintiff's favor." Coal. for Competitive Elec. v. Zibelman, 906 F.3d 41, 48-49 (2d Cir. 2018) (citation omitted). But "allegations that are conclusory are not entitled to be assumed true." Lynch v. City of New York, 952 F.3d 67, 75 (2d Cir. 2020) (citation omitted).

I. Section 13(b) of the FTC Act

The defendants argue that, because the alleged violation of law is not ongoing, the FTC lacks authority to bring this lawsuit in federal district court. Pursuant to § 13(b) of the FTC Act, the FTC is a proper party to this lawsuit.

The FTC Act declares "[u]nfair methods of competition" to be unlawful, 15 U.S.C. § 45(a), and directs the FTC to prevent violations of the FTC Act. "Unfair methods of competition" under the FTC Act, id., encompass violations of the Sherman Act. FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 454 (1986).

The FTC may combat unfair methods of competition by initiating administrative proceedings or, in some cases, by bringing lawsuits in federal court. See 15 U.S.C. §§ 45(b),

53(b). The FTC may bring an administrative complaint when it has "reason to believe" that a defendant "has been or is using" unfair methods of competition. 15 U.S.C. § 45(b). By contrast, § 13(b) of the FTC Act authorizes the FTC to file suit in federal district court when it "has reason to believe" a defendant "is violating, or is about to violate" the antitrust laws. 15 U.S.C. § 53(b).

In relevant part, § 13(b) provides:

Whenever the [FTC] has reason to believe --

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the [FTC], and

(2) that the enjoining thereof pending the issuance of a complaint by the [FTC] and until such complaint is dismissed by the [FTC] or set aside by the court on review, or until the order of the [FTC] made thereon has become final, would be in the interest of the public --

the [FTC] . . . may bring suit in a district court of the United States to enjoin any such act or practice.

15 U.S.C. § 53(b) (emphasis supplied).

The Amended Complaint adequately alleges that, as of the time it filed this lawsuit, the FTC had reason to believe that the defendants were at that very moment actively engaged in the violations of the provisions of the Sherman Act on which the FTC is relying to bring this action. It describes an unlawful scheme devised by the defendants, which the defendants continued

to execute and which continued to have an anticompetitive impact on generic competition with Daraprim through the date of filing.

Relying on FTC v. Shire ViroPharma, Inc., 917 F.3d 147 (3d Cir. 2019), the defendants argue that the FTC lacks authority under § 13(b) to bring this lawsuit. In Shire, the Third Circuit considered whether § 13(b) authorizes the FTC to bring a lawsuit in federal district court based on “long-past conduct without some evidence that the defendant ‘is’ committing or ‘is about to’ commit another violation.” Id. at 156. Five years prior to the filing of the FTC action, the defendant in Shire had inundated the FDA with meritless filings in order to delay FDA approval of generic competitors to a drug owned by the defendant. Id. at 149. By the time the FTC filed suit, the defendant had divested itself of the drug. Id.

In concluding that § 13(b) did not authorize the FTC’s lawsuit in those circumstances, the Third Circuit relied both on the plain language of § 13(b) as well as its legislative history. The Third Circuit determined that § 13(b)’s language “unambiguous[ly]” prohibits “existing or impending conduct.” Id. at 156. The Third Circuit also noted that Congress added § 13(b) to the FTC Act in 1973 to enable the “FTC to bring an ‘immediate halt to unfair or deceptive acts or practices’ when at the present time such practices might continue for several

years until agency action is completed.’’ Id. (quoting S. Rep. No. 93-151, at 30 (1973)).

The defendants contend that the allegations in the Amended Complaint address past conduct to forestall generic competition to Daraprim, and, as such, cannot support a finding that any defendant “is violating, or is about to violate” the antitrust laws. 15 U.S.C. § 53(b). In so arguing, the defendants overread Shire and ignore significant differences between the facts of Shire and the allegations in the Amended Complaint.

In Shire, the misconduct had ended, and the FTC did not assert that the defendant was “currently” violating the law. 917 F.3d at 160. Here, the FTC does contend that the defendants are currently engaged in violations of federal antitrust laws, or, at the very least, that it has sufficient “reason to believe” that the defendants are engaging in violations of federal antitrust laws. 15 U.S.C. § 53(b). Among other things, most of Vyera’s anticompetitive contracts are still in effect. The network of contracts remains sufficiently robust to impede competition to this day and to allow Vyera to continue to sell Daraprim at \$750 per pill.

The defendants emphasize that the negotiation and execution of the contracts occurred prior to the filing of this action. This argument is meritless. The FTC is not required to bring suit at the exact moment contractual negotiations ripen into

executed contracts. It is the extant scheme that provides the basis for the lawsuit.

The defendants also note that one generic competitor has -- after seven years of trying -- won FDA approval to produce and sell a generic competitor to Daraprim. This hard-won approval does not immunize the defendants from antitrust liability. As already explained, the alleged scheme continues. Moreover, a restraint of trade need not "completely block[]" competition to be unlawful. United States v. Microsoft Corp., 253 F.3d 34, 64 (D.C. Cir. 2001); see also New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 656 (2d Cir. 2015) ("Namenda II") ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." (citation omitted)). In any event, the FDA approval did not come before this lawsuit was filed.

For the same reasons, the Individual Defendants' argument that the Amended Complaint lacks allegations that either Shkreli or Mulleady are violating or are about to violate the law also fails. The Amended Complaint alleges that the Individual Defendants designed and implemented Vyera's competition-blocking system and that that system remains in place. The Amended Complaint also alleges that Shkreli and Mulleady still hold leadership positions and decision-making power at Vyera.

In sum, the FTC has alleged that the Individual Defendants, as well as Vyera, were still engaged in the alleged violations of the antitrust laws as of the date that the FTC filed this lawsuit. Section 13(b) therefore provides the FTC with the authority to file this lawsuit in federal court.

II. Section 63(12) of New York Executive Law

The defendants seek dismissal of the claims brought pursuant to § 63(12) of New York Executive Law, which authorizes the New York Attorney General to seek equitable relief. In relevant part, § 63(1) provides:

Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages The term "persistent fraud" or "illegality" as used herein shall include continuance or carrying on of any fraudulent or illegal act or conduct. The term "repeated" as used herein shall include repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person.

N.Y. Exec. Law § 63(12) (emphasis supplied). Thus, the New York Attorney General may seek equitable relief for either (1) "repeated fraudulent or illegal acts," or (2) "persistent fraud or illegality in the carrying on, conducting or transaction of business." Id.

The defendants seek dismissal of the § 63(12) claim on the ground that the Amended Complaint does not allege any continuing violations of the law. This argument ignores the statutory provision making “repeated” violations of the law actionable. In any event, for the same reasons discussed in connection with the defendants’ challenge to the FTC’s authority to bring this action pursuant to § 13(b) of the FTC Act, the Amended Complaint adequately alleges that the illegality persists.

III. Federal Antitrust Claims

The defendants argue that the Amended Complaint fails to adequately allege violations of §§ 1 and 2 of the Sherman Act.⁷

A. Section 1 of the Sherman Act

Section 1 of the Sherman Act prohibits restraints on trade effected by a contract, combination, or conspiracy. US Airways, Inc. v. Sabre Holdings Corp., 938 F.3d 43, 54 (2d Cir. 2019).

To prove a § 1 violation, a plaintiff must show that there were “concerted actions between at least two legally distinct economic entities” which evince “a conscious commitment to a common scheme designed to achieve an unlawful objective.”

United States v. Apple, Inc., 791 F.3d 290, 313, 315 (2d Cir. 2015) (citation omitted). The “crucial question” in a Section 1

⁷ The defendants have not argued that the state antitrust claims may be dismissed if the federal antitrust claims survive.

case is whether "the challenged conduct stems from independent decision or from an agreement, tacit or express." Id. at 314-15 (citation omitted).

At the pleading stage, a plaintiff must allege enough facts to support the inference that a conspiracy existed. Mayor and City Council of Baltimore, Md. v. Citigroup, Inc., 709 F.3d 129, 136 (2d Cir. 2013). "While for purposes of a summary judgment motion, a Section 1 plaintiff must offer evidence that tends to rule out the possibility that the defendants were acting independently, to survive a motion to dismiss, . . . a plaintiff need only allege enough factual matter (taken as true) to suggest that an agreement was made." Starr v. Sony BMG Music Entm't, 592 F.3d 314, 321 (2d Cir. 2010) (citation omitted).

To prove the existence of a conspiracy, parallel action is not, by itself, sufficient. Apple, 791 F.3d at 315. But, "the existence of additional circumstances, often referred to as 'plus' factors . . . when viewed in conjunction with the parallel acts, can serve to allow a fact-finder to infer a conspiracy." Id. (citation omitted). These additional circumstances can consist of "direct evidence that the defendants entered into an agreement," or "circumstantial facts supporting the inference that a conspiracy existed." Id. (citation omitted). "Circumstances that may raise an inference of conspiracy include a common motive to conspire, evidence that

shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications." Id. (citation omitted).

Once a plaintiff has adequately alleged concerted action, the plaintiff must allege that the concerted action "constituted an unreasonable restraint of trade." Anderson News, L.L.C. v. Am. Media, Inc., 899 F.3d 87, 97 (2d Cir. 2018) (Anderson II) (citation omitted). A restraint of trade may be per se unreasonable or unreasonable under the rule of reason. Id. The plaintiffs assert a violation that is assessed under the rule of reason.

The rule of reason analysis requires a court to weigh "the relevant circumstances of a case to decide whether a restrictive practice constitutes an unreasonable restraint on competition." Anderson News, L.L.C. v. Am. Media, Inc., 680 F.3d 162, 192 (2d Cir. 2012) (Anderson I) (citation omitted). Such factors may include "specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). At the pleading stage, a plaintiff must allege a "relevant market," as well as an "adverse effect on competition." Elecs. Commc'ns v. Toshiba Am. Consumer Prods., Inc., 129 F.3d 240, 244 (2d Cir. 1997). "The true test

of legality under § 1 of the Sherman Act is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” Apple, 791 F.3d at 322 (citation omitted).

The Amended Complaint identifies the relevant market as the market for pyrimethamine products that have received FDA approval for sale in the United States. It plausibly alleges that Vyera orchestrated a conspiracy with its suppliers and distributors with the purpose of blocking competitors from entering the relevant market, thereby maintaining the inflated price of Daraprim. The specific information regarding the conspiracy that is recited in the Amended Complaint includes the terms of Vyera’s contracts, the number of those contracts, and the context in which each of them was entered and maintained. The contract terms include provisions precluding sales to Vyera’s generic pharmaceutical competitors, limiting the quantity of product of both Daraprim and API available for repurchase, and paying distributors to limit access to market data. In return for agreeing to these restrictive terms, Vyera paid its distributors a percentage of Daraprim’s WAC and paid at least one of its suppliers a percentage of its net revenues of Daraprim. The higher the price of Daraprim, thus, the more Vyera’s alleged co-conspirators would benefit from each sale.

In addition to describing these contractual terms, the Amended Complaint recites conversations with co-conspirators acknowledging Vyera's purpose to block competition by generic drug manufacturers.

The Amended Complaint also adequately alleges that the restrictive distribution system, the exclusive supply contracts, and the data-blocking agreements are unreasonable restraints of trade that adversely affect competition in the relevant market. This alleged conspiracy struck at the heart of the American pharmaceutical market for pyrimethamine and more generally the regulatory framework established to promote the supply and affordability of pharmaceuticals. The regulatory framework is designed to encourage substitution of generic equivalents for branded drugs and assumes access to branded drugs for bioequivalence testing and to approved API manufacturers. As alleged, Vyera's agreements impeded competitors from obtaining expedited ANDA approval. They blocked competitors from obtaining access to approved API manufacturers and sufficient supplies of Daraprim. The data-blocking agreements made it difficult for competitors to assess the market size of Daraprim and determine whether to invest in the development of a generic substitute for Daraprim.

Not only is it alleged that the purpose of these agreements was to block competition, it is also alleged that the

conspirators succeeded in accomplishing that purpose. The Amended Complaint explains how multiple manufacturers of generic pharmaceuticals that wish to compete with Vyera have been delayed for years in obtaining FDA approval because of their inability to obtain Daraprim for bioequivalence testing and API from an FDA-approved manufacturer. And of course, Vyera continues to sell Daraprim at the inflated price of \$750 per tablet.⁸

In arguing for dismissal of the § 1 claim, the defendants challenge the sufficiency of the pleadings as to both concerted action and the adverse effect on competition. They do not dispute that the relevant market is the market for FDA-approved pyrimethamine products for sale in the United States.

With respect to concerted action, the defendants argue that the § 1 claim does not adequately allege that Vyera's distributors and pyrimethamine suppliers shared Vyera's anticompetitive goal. They contend that the Amended Complaint lacks allegations that the distributors and suppliers stood to benefit from the alleged anticompetitive scheme or had knowledge of Vyera's anticompetitive intent. The defendants are wrong. The restrictive terms of the contracts described above,

⁸ See Astrazeneca AB, 985 F. Supp. 2d. at 502-03 (describing the gradual decline in prices that occurs when multiple generic competitors, over time, enter a market previously occupied by a single branded drug).

especially when combined with Vyera's radical pricing strategy, made it obvious to Vyera's commercial partners that they were agreeing to engage in anticompetitive conduct by executing those agreements. Because the distributors and at least one supplier, RL Fine, were paid a percentage of Daraprim's WAC and Vyera's net annual revenue, respectively, the more extravagantly-priced Daraprim Vyera sold, the more the coconspirators stood to gain. In addition, Vyera openly discussed with several coconspirators, including its other supplier, Fukuzyu, its intention to block generic competition. Finally, Vyera's illicit goal was public knowledge as early as November 2015, when the Senate Special Committee's investigation was launched.

Next, the defendants contend that the § 1 claim does not plausibly allege an adverse effect on competition. In particular, the defendants argue that Vyera was under no obligation to sell Daraprim to its competitors. While a seller "generally has a right to deal, or refuse to deal, with whomever it likes," it may do so only "as long as it does so independently." Anderson I, 680 F.3d at 183 (emphasis in original); see also United States v. A. Shrader's Son, Inc., 252 U.S. 85, 99 (1920) (noting that a seller may not "destroy [its] dealers' independent discretion through restrictive agreements"). Vyera used contractual restrictions on its distributors' sales (and on their customers' sales), as

described above, to coordinate the scheme to block generic competition and maintain Daraprim's inflated price. This Vyera is not permitted to do. See Monsanto Co. v. Stray-Rite Service Corp., 465 U.S. 752, 761 (1984); United States v. Colgate & Co., 250 U.S. 300, 306-07 (1919).

Similarly, the defendants contend that the plaintiffs have failed to adequately allege that Vyera's exclusive supply agreements harm competition. While it is true that exclusive dealing arrangements may have "pro-competitive purposes and effects, such as assuring steady supply, affording protection against price fluctuations, reducing selling expenses, and promoting stable, long-term business relationships," Geneva Pharm. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 508 (2d Cir. 2004), the Amended Complaint alleges that Vyera's exclusive supply contracts had anti-competitive purposes. For instance, the Amended Complaint alleges that Vyera contracted with RL Fine for an exclusive supply of its pyrimethamine even though Fukuzyu reliably produces more pyrimethamine than Vyera orders or can use. The Amended Complaint also alleges that Vyera invoked its contracts with its suppliers to prevent them from supplying pyrimethamine to competitors. Because access to FDA-approved manufacturers of pyrimethamine was blocked by Vyera, potential competitors were delayed as they sought FDA approval for a generic competitor to Daraprim. See id. at 508-09 (exclusive

supply agreement between a drug-maker and API supplier allowed the supplier to control the “entire supply” of the API and “freeze competitors out” of the generic drug market); see also Namenda II, 787 F.3d at 656 (“The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market’s ambit.” (citation omitted)).⁹

Finally, the defendants argue that the existence of the data-blocking agreements does not support the antitrust claim because information on market size is “readily accessible” from the decades over which Daraprim has been sold and from data about the incidence of the infection that may be treated with Daraprim. The allegations regarding these agreements support the plaintiffs’ allegations more generally regarding the defendants’ anti-competitive intent. The determination of

⁹ The defendants also argue that Vyera’s exclusive supply contract with Fukuzyu is not harmful to competition because its term was set at a limited number of years. A fact-finder will assess the anti-competitive effect of this and the other Vyera contracts at a later stage of this litigation. The Fukuzyu contract, however, includes an automatic annual renewal term and remains in place today. In any event, that contract was just one facet of the overarching scheme and there is no requirement that a scheme to thwart competition run beyond a particular number of months or years to be actionable.

whether these agreements materially impacted the ability of generic competitors to enter the market must await trial.¹⁰

B. Section 2 of the Sherman Act

Section 2 of the Sherman Act provides that it is unlawful to “monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States, or with foreign nations.” 15 U.S.C. § 2. “To safeguard the incentive to innovate, the possession of monopoly power” is not found unlawful, however, “unless it is accompanied by an element of anticompetitive conduct” -- that is conduct lacking a “legitimate business purpose” that makes sense “only because it eliminates competition.” In re Adderall XR Antitrust Litig., 754 F.3d 128, 133 (2d Cir. 2014) (citation omitted). A plaintiff asserting a monopolization claim must allege both: (1) “the possession of monopoly power in the relevant market,” and (2) “the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” Id. (citation omitted); see also Geneva, 386 F.3d at 495.

¹⁰ The defendants note that between 2014 and 2019, three generic competitors filed ANDA applications. Section 1 forbids a conspiracy to restrain competition even where that conspiracy is not completely successful.

It is not disputed that the Amended Complaint adequately alleges Vyera's monopoly power in the market for FDA-approved pyrimethamine products for sale in the United States. For the same reasons just discussed in connection with the motion to dismiss the § 1 claim, the Amended Complaint adequately alleges that the defendants willfully engaged in anticompetitive conduct to maintain that monopoly.

In arguing to the contrary, the defendants argue that they have no duty to transact business with a competitor. "The absence of a duty to transact business with another firm is, in some respects, merely the counterpart of the independent businessman's cherished right to select his customers and associates," as recognized under § 1 of the Sherman Act. Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 601 & n.27 (1985) (citing Monsanto, 465 U.S. at 761, and Colgate, 250 U.S. at 370.). As with § 1 cases, this right is not "unqualified." Id. at 601. The right does not permit action taken for the purpose of creating or maintaining monopoly power. Id.

The Amended Complaint alleges that Vyera, while holding a monopoly, prohibited any sales of Daraprim, directly or indirectly, to generic pharmaceutical competitors and even re-purchased Daraprim at above-retail prices to stymie competitors' access to Daraprim. The Amended Complaint further alleges that

Vyera did so because access to Daraprim was, by regulation, necessary for potential competitors to enter the market. These allegations plausibly plead that the defendants blocked competitors from accessing Daraprim for the purpose of maintaining their monopoly. See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 410 (2004).

The other arguments the defendants make to challenge the plaintiffs' § 2 claim repeat those they presented to the § 1 claim. For the same reasons, those objections are rejected. See, e.g., E&L Consulting, Ltd. v. Doman Indus. Ltd., 472 F.3d 23, 31 (2d Cir. 2006) ("A viable claim under Section 2 challenging a distributorship agreement must, like a Section 1 claim, show harm to competition."); see also Microsoft, 253 F.3d at 59 ("[T]he analysis under [S]ection 2 is similar to [the rule of reason analysis] under [S]ection 1.").

C. Sherman Act Claims Against the Individual Defendants

Shkreli and Mulleady argue that even if the Amended Complaint plausibly alleges that Vyera violated the Sherman Act, the Sherman Act claims against them should be dismissed. An individual may be held liable under the Sherman Act to the extent that individual has "participated in violations of" the antitrust laws, such as by "negotiating, voting for[,] or executing agreements which constituted steps in the progress of the conspiracy." Hartford-Empire Co. v. United States, 323 U.S.

386, 407 (1945); see also Lorain Journal Co. v. United States, 342 U.S. 143, 145 n.2 (officers and directors "participated in the conduct alleged to constitute the attempt to monopolize").

According to the Amended Complaint, Shkreli is Phoenixus's largest shareholder and the founder and former CEO of Vyera, and Mulleady is Phoenixus's chairman of the board and the former CEO of Vyera. The Amended Complaint alleges that they not only participated in the anticompetitive conduct at issue, but also designed, implemented, and negotiated the network of contracts that block generic competition to Daraprim.

The Individual Defendants argue that the Amended Complaint must allege that they, as individuals, conspired with Vyera's distributors or suppliers for purposes of the plaintiffs' § 1 claim, or that they, as individuals, possessed monopoly power, for purposes of the plaintiffs' § 2 claim. Not so. Performing the activities described in the Amended Complaint as corporate officers and agents is sufficient to subject them to liability for antitrust violations. Moreover, they benefitted personally from the illegality to the extent Vyera benefitted and their intent to benefit Vyera establishes as well their intent to benefit themselves through that wrongdoing.

IV. Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL")

The defendants seek dismissal of the Pennsylvania UTPCPL claim. The Pennsylvania UTPCPL, 73 Pa. Stat. Ann. § 201-1 et seq., "is designed to protect the public from fraud and deceptive business practices." Belmont v. MB Inv. Partners, Inc., 708 F.3d 470, 497 (3d Cir., 2013) (citation omitted). The UTPCPL makes unlawful "unfair methods of competition" and "unfair or deceptive acts or practices." 73 Pa. Stat. Ann. § 201-2(4). The statute defines these terms as twenty specific prohibited practices, id. § 201-2(4)(i)-(xx), and adds a catchall provision that prohibits "any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." Id. § 201-2(4)(xxi); see also Belmont, 708 F.3d at 497-98. The Amended Complaint relies on the catchall provision as the basis for its UTPCPL claim.

The Commonwealth Court of Pennsylvania recently considered whether the UTPCPL should be interpreted "to render all antitrust violations actionable." Anadarko Petroleum Corp. v. Commonwealth, 206 A.3d 51, 60 (Pa. Commw. Ct. 2019).¹¹ It

¹¹ The court in Anadarko held that the Commonwealth could not allege that the defendants' joint venture and market sharing agreements violated the UTPCPL because the conduct did not meet the statutory definition of the catchall provision. 206 A.3d at 61. The court determined that other claims, which alleged "disingenuous and misleading behavior," were viable under the UTPCPL because they did meet this statutory definition. Id. at

determined that "the scope of actionable antitrust behavior under the UTPCPL is narrower than under federal antitrust law" because the Pennsylvania General Assembly has declined to use its "powers to expressly define monopolistic behavior," among other conduct deemed anticompetitive under the federal antitrust laws, as an "unfair method[] of competition" or an "unfair or deceptive act[] or practice[]" for purposes of the UTPCPL.¹² Id. The court in Anadarko determined that the "only manner in which [such] activities can give rise to viable UTPCPL actions is if they fit within one of the categories of behavior" that the UTPCPL expressly deems an "unfair method[] of competition" or an "unfair or deceptive act[] or practice[]." Id.

The Amended Complaint does not adequately allege that the anticompetitive conduct it describes is "fraudulent," "deceptive," or likely to create "confusion" or "misunderstanding." 73 Pa. Stat. Ann. § 201-2(4)(xxi). In

62. The decision permitting those claims to survive is being reviewed on appeal. Commonwealth v. Chesapeake Energy Corp., 218 A.3d 1205 (Pa. 2019) (per curiam).

¹² The Pennsylvania Attorney General also may promulgate definitions of the terms "unfair methods of competition" and "unfair or deceptive acts or practices" through administrative rulemaking. 73 Pa. Stat. Ann. § 201-3.1. The court in Anadarko noted that the Pennsylvania Attorney General, like the Pennsylvania General Assembly, has declined to expand the definition of these terms to cover the full panoply of conduct deemed unlawful under the federal antitrust laws. 206 A.3d at 60-61.

fact, it asserts that Vyera informed its distributors and suppliers of the purpose behind its desired contractual terms, and Vyera executives testified before the Senate about their intention to prevent potential competitors from obtaining enough Daraprim to conduct bioequivalence testing.

In opposing dismissal of the UTPCPL claim, the plaintiffs do not address the holding of Anadarko and repeatedly warn against defining the term "fraud" as contained in the residual clause of § 201-2(4) (xxi) too narrowly, noting that fraud has a "broader meaning in equity." But, the plaintiffs fail to cite any precedent suggesting that the conduct at issue here is "fraudulent" for purposes of the residual clause of the UTPCPL. This Court declines to expand the plain terms of the statute.¹³

V. Damages

Next, the Individual Defendants argue that certain state law claims -- those brought under the New York Executive Law, New York's Donnelly Act, and Ohio's Valentine Act -- must be dismissed to the extent they seek damages. They contend that when the New York Attorney General sues for damages on behalf of a government entity under the New York Executive Law or Donnelly

¹³ While the plaintiffs argue that they have pleaded "constructive fraud," they do not explain how the conduct at issue qualifies as constructive fraud, nor do they provide any authority suggesting that the reference to fraudulent conduct in the catchall provision of the UTPCPL should be interpreted to encompass constructive fraud.

Act, the Attorney General must specify the government entity upon whose behalf she brings the suit, and that she has failed to do so here. See N.Y. Gen. Bus. Law § 342-b; N.Y. Exec. Law § 63. The Individual Defendants also contend that New York may not seek damages on behalf of natural persons under the Donnelly Act, and that Ohio may not seek damages on behalf of indirect purchasers under the Valentine Act.

These arguments fail for the simple reason that the plaintiffs in this action do not seek damages; they seek equitable monetary relief. This they are allowed to do. See N.Y. Gen. Bus. Law § 342; N.Y. Exec. Law § 63; Georgia v. Pa. R. Co., 324 U.S. 439, 447 (1945); O.R.C. Chapter 1331.11; O.R.C. § 109.81.

VI. Equitable Monetary Relief

The Individual Defendants also take issue with the demand for equitable monetary relief. They argue that the Amended Complaint fails to allege that they have unjustly gained as a result of the alleged misconduct, and that, in any event, the plaintiffs have not given them "fair notice" of the type of equitable monetary relief they seek -- "whether restitution, disgorgement, or some form of damages."

These arguments also fail. First, the Amended Complaint alleges that both Shkreli and Mulleady have directly benefitted from Vyera's ill-gotten gains, including as shareholders.

Second, “courts have routinely deprived wrongdoers of their net profits from unlawful activity, even though that remedy may have gone by different names.” Liu v. Securities and Exchange Commission, 140 S. Ct. 1936, 1942-43 (2020) (noting that “restitution” is frequently called “disgorgement”). At this stage, the Amended Complaint provides sufficient notice to the Individual Defendants of the plaintiffs’ claims against them, as well as the plaintiffs’ requested relief.

VII. Statute of Limitations

Finally, Shkreli argues that the four-year statutes of limitations that apply to laws underlying certain claims in the Amended Complaint bar those claims when brought against him. These include the Sherman Act claims as well as the state law claims of New York, California, Illinois, North Carolina, Ohio, and Virginia. This argument is rejected.

The Amended Complaint alleges that Shkreli has participated in conduct that is illegal under each of the laws within the four-year period that preceded the filing of this action. For instance, it asserts that he worked as recently as August 2017 to cause Vyera to enter an exclusive supply contract with RL Fine, and in August 2019 he strategized with Mulleady about restricting Daraprim sales to one bottle at a time to impede competitors in their efforts to conduct bioequivalence testing. And, of course, it alleges that Shkreli played a critical role

in the design and execution of contracts at the heart of this scheme that remained in effect as of the date this action was filed. While Shkreli may have lost his official title as an officer or director of Vyera upon his arrest in 2015, his liability hinges not on his title, but on his involvement and participation in Vyera's unlawful scheme.

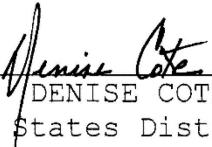
Moreover, there is no statute of limitations for a § 13(b) claim, which as described above, requires ongoing illegal activity at the time the claim is brought. While § 4 of the Clayton Act, 15 U.S.C. § 15b, provides a four-year statute of limitations for a damages action, the FTC's claims for equitable relief under § 13(b) of the FTC Act are not subject to a statute of limitations. See Fed. Trade Comm'n v. Credit Bureau Ctr., LLC, 937 F.3d 764, 783 (7th Cir. 2019) ("[S]ection 13b has no statute of limitations."); see also F.T.C. v. Instant Response Sys., LLC, No. 13cv976 (ILG), 2014 WL 558688, at *3 (E.D.N.Y. Feb. 11, 2014) ("[C]ourts have universally rejected arguments that statutes of limitations from other provisions of the FTCA apply to [§ 13b], the provision authorizing the FTC's suit on these counts.").

Conclusion

The defendants' May 22, 2020 motions to dismiss are granted as to the Pennsylvania UTPCPL claim. As to all of the other

claims in the Amended Complaint, the May 22 motions to dismiss are denied.

Dated: New York, New York
August 18, 2020



DENISE COTE
United States District Judge